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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,478	11/17/2000	Beth Anne Allison	2196/1E500	7552

25225 7590 11/05/2002

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/05/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/715,478

Applicant(s)

ALLISON ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 21, 2002 has been entered.

The amendments filed June 24, 2002 have been entered.

The outstanding rejections under 35 USC 112, first and second paragraph are withdrawn in view of the amendments filed June 24, 2002.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 12-19 of U.S. Patent

No. 09/716,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only two differences between the sets of claims are that 1) the claims in the instant application recite the specific dosing range (0.25 – 25J/cm²); and 2) the instant claims employ the photodynamic agents within a specific time of angioplasty procedure. One of ordinary skill in the art would have been motivated to employ the specific herein claimed dosage regimen because optimization of dosing regimen is obvious as being within the skilled artisan. Furthermore, angioplasty is a common procedure employed to treat restenosis or intimal hyperplasia.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “prevent” in claim 1 renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent restenosis or intimal hyperplasia are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of restenosis or intimal hyperplasia would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some

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prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vincent'362 (US Patent 5,422,362, reference of record) and Vincent et al. (Progress in biomedical Optics, Proceedings of Laser in surgery: Advanced Characterization, Therapeutics, and Systems VI, 1996, vol. 2671, page 72-77).

Vincent'362 teaches a method to prevent or inhibit intimal hyperplasia in adjunct with angioplasty in a subject with the administration of BPD-MA concurrent with or within 6 hours of the injury and following the angioplasty. Vincent'362 also teaches that the BPD-MA is administered to the angioplasty-injured site (See abstract; also col.10,

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example 1; and claims 1-22). Vincent'362 also teaches that the method is applicable to various angioplasty procedures broadly including any procedure which involves traumatic manipulation of the vasculature (See col. 3, line 62 – col. 4, line 4).

Vincent'362 also teaches the presence of smooth muscle cells after the BPD-MA therapy, i.e., without depleting all cells at the site (See particularly col. 11, line 16-19).

Vincent'362 also teaches the use of Photofrin II, also known as porfimer sodium, in the concentration of $2\mu\text{g/ml}$, to treat restenosis with light energy of greater than 3 J/cm^2 .

Such treatment results in the destruction of over 80% of smooth muscle cells (See col. 2, line 40-57).

Vincent et al. teaches a method of treating restenosis in adjunct with angioplasty in a subject with the administration of 2mg/kg of BPD-MA with irradiation, concurrent with or within 15 minutes of the angioplasty procedure (See the abstract, also 73, Sections 2.2 and 2.3). Vincent et al. also teaches the 30J/cm^2 of irradiation is used (See page 73, fourth paragraph). Vincent et al. also teaches that the smooth muscle cells are not totally eradicated (See the abstract, and Section 3.2.5 in page 75).

The references do not expressly teach the irradiation employed as about 0.25 to about 25 J/cm^2 .

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply radiation of about 0.25 to about 25 J/cm^2 in the method of treating restenosis using BPD-MA.

One of ordinary skill in the art would have been motivated to employ radiation of about 0.25 to about 25 J/cm^2 in the method of treating restenosis using BPD-MA.

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Based on the teachings of Vincent et al., $30\text{J}/\text{cm}^2$ is known to be effective in treating restenosis and not totally destruct smooth muscle cells. Therefore, applying light energy of about 0.25 to about $25\text{ J}/\text{cm}^2$ would simply be considered as optimization of result therapeutic parameters (dosing regimens e.g., dosing of light energy), which is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

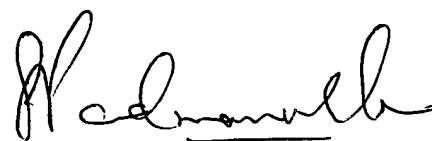
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui
October 30, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

11/3/03